BROOKSTEIN DECLARATION EXHIBIT 15

FiberWire™

IMPORTANT PRODUCT INFORMATION
WICHTIGE PRODUKTINFORMATION
NOTICE D'UTILISATION IMPORTANTE
IMPORTANTI INFORMAZIONI PER L'USO
INSTRUCCIONES IMPORTANTES PARA EL USO

CE 0086

Arthrex

Manufacturer:
Arthrex Inc.
Naples, Florida 34108-1945 • USA
Toll-Free: +1 800 934-4404
www.arthrex.com

E. C. Representative:
Arthrex Med. Inst. GmbH
85757 Karlsfeld
Germany
Tel: +49 81 31 59 57 0 • Fax: +49 81 31 58 57 63 1

Arthrex

DFU-0085
Rev. B

Description:
Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:
Arthrex FiberWire is indicated for use in soft tissue approximation and or ligation. FiberWire is not for use in cardiac indications.

Actions:
Arthrex FiberWire, when tested per ISO/DIS 10993, *Biological Evaluation of Medical Devices-Part 10: Tests for Irritations and Sensitization*, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:
None known

Warnings:
Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharps" containers.

Adverse Reactions:
Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:
Arthrex FiberWire suture is supplied sterile.
Method of sterilization - EO
Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:
Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:
The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

Do not reuse	QTY Quantity
STERILE EO Sterile unless the package is damaged or open. Method of sterilization - EO	
STERILE R Sterile unless the package is damaged or open. Method of sterilization - gamma radiation	
LOT Lot number	See package insert
CE The product meets the essential requirements of Medical Device Directive 93/42 EEC.	
Use by - year & month	

Beschreibung:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (gesenkgeschmiedeten) Nadeln unterschiedlicher Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:
Arthrex FiberWire ist für Weichgewebeapproximation und/oder -ligation vorgesehen. FiberWire nicht für Kardio-Indikationen verwenden.

Funktionen:
Tests bei Arthrex FiberWire gemäß ISO/DIS 10993, *Biological Evaluation of Medical Devices - Part 10: Reiz- und Sensibilisierungstests* ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde *in vivo* keine signifikante Änderung der Zerreißfestigkeit festgestellt.

Gegenanzeigen:
Unbekannt

Warnhinweise:
Nicht resterilisieren. Unbenutztes Fadenmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschließen von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbarer Faden verwendet wird, da das Dehiszenzrisiko je nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Salzlösungen, (wie sie z.B. im Harn- und Gallentrakt vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von infizierten oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:
Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schäden durch Zusammendrücken oder Abklemmen mit chirurgischen Instrumenten wie Zangen oder Nadelhaltern nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Knotenhaltbarkeit ist die Verwendung von flachen, quadratischen Schleifen mit zusätzlichen Verknotungen, je nach chirurgischer Situation und Erfahrung des Chirurgen. Besonders beim Verknoten von monofilen Fäden sind unter Umständen zusätzliche Verknotungen angebracht. Sorgfältig vorgehen, um Schäden am umgebenden Gewebe und Benutzerpunktierung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Umformen an Stärke verlieren und gegen Verbiegen und Abbrechen weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:
Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Faden üblichen Reaktionen zählen unter Umständen Dehiszenz, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Salzlösungen (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeentzündungen, Schmerzen, Ödeme und Erythema an der Wundstelle. Versehentliches Stechen mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:
Arthrex FiberWire wird steril geliefert.
Sterilisationsmethode - EO.
Nicht resterilisieren. Bei beschädigter oder zuvor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

Lagerungsbedingungen:
Unter 25 °C trocken und fern von direkter Hitzeeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadenmaterial wird steril in vorgeschnittenen Längen und in manchen Fällen mit gesenkgeschmiedeten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

Nicht wiederverwendet	QTY Quantität
STERILE EO Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - EO	
STERILE R Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - Bestrahlung	
LOT Chargenbezeichnung	Siehe Packungsbeilage
CE Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates über Medizinprodukte 93/42/EWG.	
Verwendbar bis Jahr und Monat	

Description:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Arthrex FiberWire est également commercialisée avec des aiguilles serties de différentes tailles. Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou teintée, et elle est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:
La suture Arthrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Arthrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Réactions:
Aucune réaction allergique ou sensible n'a été observée lors de la soumission de la suture Arthrex FiberWire au test exigé par la norme ISO/DIS 10993 *(Evaluation biologique des dispositifs médicaux, Partie 10 : Essais d'irritation et de sensibilisation*. La suture teintée et le traitement en surface de la suture sont pharmacologiquement inactifs.

La suture Arthrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Arthrex FiberWire ne change pas de manière significative *in vivo*.

Contre-indications:
Aucune contre-indication connue.

Précautions d'emploi:
Ne pas stériliser à nouveau. Jeter toute suture non utilisée dont l'emballage a été ouvert. Ne pas exposer à la chaleur.

Tout praticien suturant une plaie avec la suture Arthrex FiberWire doit être familiarisé aux techniques chirurgicales recommandées pour les matériaux non résorbables, car le risque de déhiscence de la plaie varie selon le site de l'intervention et selon le type de suture employé.

Comme avec tout matériau exogène, un contact prolongé de cette suture ou de tout autre fil avec un fluide salin, comme ceux circulant dans les voies urinaires ou biliaires, peut conduire à la formation de calculs. Le praticien devra respecter les règles chirurgicales relatives au drainage et à la fermeture de plaies infectées ou contaminées.

Précautions d'emploi:
Comme avec toute autre suture, éviter d'abîmer le fil lors de sa manipulation. Ne pas écraser le fil avec des instruments chirurgicaux comme une pince ou un porte-aiguille.

Réaliser tous les nœuds conformément aux techniques chirurgicales en vigueur. Opter pour le nœud plat, qui garantit une bonne sécurité et qui est largement utilisé, avec boucles supplémentaires en fonction du cas chirurgical et de l'expérience du praticien. Si le fil est monofilament, prévoir des boucles supplémentaires pour les nœuds.

Bien contrôler la pointe de l'aiguille pour éviter de piquer les tissus environnants ou de blesser le praticien.

Ne pas saisir l'aiguille par sa pointe ou par son attache sur le fil pour éviter de l'endommager. Eviter de modifier la courbure des aiguilles pour ne pas réduire leur résistance à la déformation et à la rupture. Après usage, jeter les aiguilles dans un récipient spécial pour objets pointus et tranchants.

Effets indésirables:
Aucun effet indésirable particulier n'a été observé lors des tests du fil Arthrex FiberWire chez l'animal. Comme avec les autres fils de suture non résorbables, les réactions suivantes sont possibles : déhiscence de la plaie, formation de calculs dans les voies urinaires ou biliaires si contact prolongé avec des fluides salins comme l'urine ou la bile, infectivité bactérienne accrue, inflammation tissulaire minime, douleur, œdème et érythème au niveau de la plaie. Toute blessure avec une aiguille chirurgicale contaminée peut transmettre des germes pathogènes présents dans le sang.

Stérilisation:
La suture Arthrex FiberWire est livrée stérile.
Méthode de stérilisation : oxyde d'éthylène
Ne pas stériliser à nouveau. Ne pas utiliser si l'emballage est ouvert ou endommagé. Jeter les sutures non utilisées si leur emballage est ouvert.

Conditions de stockage:
Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différentes longueurs précoupées. Elle est aussi disponible avec des aiguilles serties. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou en couleurs (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

SYMBOLES UTILISÉS SUR L'ÉTIQUETAGE

Ne pas réutiliser — QTY Quantité
STERILE EO Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - EO
STERILE R Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - irradiation
LOT No. de lot — Consulter la notice accompagnant le produit
CE Ce produit est conforme aux exigences de la directive sur les dispositifs médicaux CEE 93/42.
À utiliser avant le (mois/année)

Descrizione:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). FiberWire Arthrex può essere venduto anche con aghi di varie dimensioni attaccati (saldati) alle estremità. La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Arthrex è disponibile sia non tinto (bianco) che tinto e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:
FiberWire Arthrex è indicato per l'approssimazione e/o la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Azioni:
FiberWire Arthrex, quando testato per ISO/DIS 10993, *Valutazione biologica dei dispositivi medici-Parte 10: I test per irritazioni e sensibilizzazione*, non hanno evidenziato reazioni allergiche o ipersensibilità. La sutura e il rivestimento tinti sono farmacologicamente inattivi.

FiberWire Arthrex non viene assorbito, ma può essere incapsulato nei tessuti connettivi circostanti. Non sono noti per FiberWire Arthrex cambiamenti significativi nella resistenza alla tensione *in-vivo*.

Controindicazioni:
Nessuna nota

Avvertenze:
Non risterilizzare. Una volta aperte, gettare le suture non utilizzate. Non esporre al calore.

Gli utenti devono conoscere bene le procedure e le tecniche chirurgiche relative alle suture non assorbibili prima di utilizzare FiberWire Arthrex per la chiusura delle ferite, in quanto il rischio di deiscenza della ferita può variare in base al sito di applicazione ed al materiale utilizzato per la sutura.

Come per qualsiasi corpo estraneo, il contatto prolungato di questa e qualsiasi altra sutura con soluzioni saline, come quelle presenti nel tratto urinario o biliare, può risultare nella formazione di calcoli. È necessario seguire una pratica chirurgica corretta per il drenaggio e la chiusura di ferite infette o contaminate.

Precauzioni:
Nel trattare questo o qualsiasi altro materiale per sutura, occorre fare attenzione ad evitare danni dovuti al maneggiamento. Evitare danni da schiacciamento o piegature dovuti all'applicazione di strumenti chirurgici, inclusi forcipi o porta-aghi.

Assicurarsi che tutti i nodi siano stati legati usando le tecniche chirurgiche di annodatura accettate. Una sicurezza adeguata del nodo richiede la tecnica chirurgica accettata di legature piatte e quadrate, nonché di ulteriori avvolgimenti in base al caso chirurgico e all'esperienza del chirurgo. L'uso di avvolgimenti aggiuntivi può essere particolarmente appropriato per l'annodamento di monofilamenti. Evitare di recare danni al tessuto circostante o alla puntura dovuti ad una manipolazione non corretta della punta dell'ago.

Non afferrare l'ago per la punta o dalla saldatura, onde evitare danni a queste aree. Il riadattamento degli aghi può indebolirli e renderli meno resistenti alle piegature ed alle rotture. Gettare gli aghi usati in contenitori per materiale «affilato».

Effetti indesiderati:
Non si sono riscontrati effetti indesiderati con l'uso del prodotto FiberWire Arthrex nei test sugli animali. Le reazioni comuni alle suture non assorbibili possono includere la deiscenza della ferita, la formazione di calcoli nei tratti urinario e biliare dovuta al contatto prolungato con soluzioni saline come urina e bile, infettività batterica elevata, minima reazione del tessuto alle infiammazioni acute, dolore, edema ed eritema al sito della ferita. Il contatto involontario dell'ago con aghi chirurgici contaminati può risultare nella trasmissione di patogeni veicolati dal sangue.

Sterilizzazione:
La sutura FiberWire Arthrex viene fornita sterile.
Metodo di sterilizzazione - EO
Non risterilizzare. Non utilizzare se la confezione è aperta o danneggiata. Gettare le suture aperte non utilizzate.

Condizioni di conservazione:
Conservare al di sotto di 25°C, lontano da umidità e calore diretto. Non utilizzare dopo la data di scadenza.

Come si presenta:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). La sutura viene fornita sterile in lunghezze pretagliate ed in alcuni casi con aghi saldati. FiberWire Arthrex è disponibile tinto o non tinto (bianco). La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

SIMBOLI USATI SULL'ETICHETTA

Monouso — QTY Quantità
STERILE EO Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - EO
STERILE R Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - Raggi Gamma
LOT Numero di lotto — Fare riferimento all'inserto contenuto nella confezione
CE Il prodotto è conforme ai requisiti essenziali della Direttiva CEE 93/42 sui Dispositivi Medici.
Da usarsi entro anno e mese

Descripción:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la sutura FiberWire de Arthrex en diversos tamaños y con agujas incorporadas (enhebradas) en los extremos. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido. La sutura FiberWire de Arthrex viene en modelos sin teñir (blanca) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:
La sutura FiberWire de Arthrex está indicada para aplicaciones de aproximación y ligadura de tejido blando. La sutura FiberWire no está indicada para uso cardíaco.

Acciones:
Sutura FiberWire de Arthrex, sometida a prueba de acuerdo con la norma ISO/DIS 10993, *Evaluación Biológica de Dispositivos Médicos-Sección 10: En pruebas para detección de irritaciones y sensibilidad*, no hubo reacciones alérgicas ni de sensibilidad. La sutura teñida y el recubrimiento son inactivos farmacológicamente.

La sutura FiberWire de Arthrex no se absorbe, pero podría encapsularse en los tejidos conjuntivos adyacentes. La sutura FiberWire de Arthrex no presenta cambios significativos conocidos en cuanto a resistencia a la tracción *in vivo*.

Contraindicaciones:
Ninguna conocida

Advertencias:
No esterilizar de nuevo. Una vez abierto el paquete, desechar la sutura no utilizada. No exponer al calor.

Los usuarios deberán conocer los procedimientos quirúrgicos y las técnicas con suturas no absorbibles antes de utilizar FiberWire de Arthrex para cerrar heridas, ya que el riesgo de dehiscencia de las heridas varía según el sitio de aplicación y el material de sutura utilizado.

Al igual que ocurre con todo cuerpo extraño, el contacto prolongado de esta sutura, o de cualquier otro tipo de sutura, con soluciones salinas como las halladas en los tractos urinario o biliar, podría producir cálculos. Se deben usar métodos quirúrgicos aceptables en relación con el drenaje y cierre de heridas infectadas o contaminadas.

Precauciones:
Se debe tener cuidado al manipular este o cualquier otro material de sutura para evitar dañarlo. No utilice instrumentos quirúrgicos o de aplicación tales como fórceps o porta-agujas para evitar aplastar o plegar el material.

Cerciórese de que todos los nudos se hayan fijado por medio de técnicas aceptadas para nudos quirúrgicos. Para la fijación correcta de los nudos es necesario utilizar la técnica quirúrgica aceptada de nudos planos y cuadrados con lazadas adicionales, según lo requieran las condiciones quirúrgicas y la experiencia del cirujano. El uso de lazadas adicionales podría ser especialmente útil en la elaboración de nudos de monofilamentos. Debe tenerse cuidado para evitar daños al tejido adyacente o punciones producidas por el usuario al manipular incorrectamente la punta de la aguja.

No sujete la aguja por la punta ni por el ojo para evitar daños en esas partes. Si se modifica la forma de las agujas, éstas podrían perder su firmeza y ser menos resistentes a las curvaturas y al rompimiento. Deseche las agujas usadas en recipientes para objetos punzantes.

Reacciones adversas:
No se han detectado reacciones adversas del producto FiberWire de Arthrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: dehiscencia de las heridas, formación de cálculos en los tractos urinario y biliar en condiciones de contacto prolongado con soluciones salinas tales como la orina y la bilis, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y eritema en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Esterilización:
La sutura FiberWire de Arthrex se suministra estéril.
Método de esterilización - EO
No esterilizar de nuevo. No utilizar si el paquete llega abierto o dañado. Desechar las suturas abiertas que no se hayan utilizado.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25° C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en cortes de longitud predeterminada y en algunos casos con agujas enhebradas. La sutura FiberWire de Arthrex se encuentra disponible en modelos sin teñir (blanca) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

SIMBOLOS UTILIZADOS EN LAS ETIQUETAS

No reutilizar — QTY Cantidad
STERILE EO Estéril mientras el envase no sea abierto o dañado Método de esterilización - EO
STERILE R Estéril mientras el envase no sea abierto o dañado. Método de esterilización - irradiación
LOT Número de lote — Ver folleto en el interior del paquete
CE Este producto cumple con las normas básicas de la Directiva de productos médicos, 93/42 CEE
Caduca - año y mes

BROOKSTEIN DECLARATION EXHIBIT 16

TO :Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 19/10/2000

SUBJECT : **Polyester - Dyneema Braid**

Dear Don,

Please find enclosed 4 DT trials samples for your inspection ,these have been made using Polyester/Dyneema mixed either in the cover or straight core, to match US2 I have set out below a matrix of how each was made and their results for your information

DT PA23 **SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER, STRAIGHT PULL CORE BROKE COVER STAYED INTACT.**

16 Carrier m/c
COVER 16 carriers in use each with 1 end of 138 d'tex Polyester per carrier
CORE I end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)
PPI 38

Stage	St/pull kg	Knot/pull kg	Runnage mt/kg	Diameter mm	Extensin %	Solids %
M/c	19.12	9.87	3455	0.677	5.48	
Dye	17.05	8.81		0.589	10	
Stretch	16.51	6.95		0.577	5.3	15.3
Finish	17.2	10.35	3375	0.569	6.8	

DEPUY MITEK
EXHIBIT 164
04cv12457

DT PA25 SAMPLE COMMENTS: BOTH CORE AND COVER BROKE ON THE STRAIGHT PULL AT DYE STAGE, ON THE STRAIGHT PULL AT STRETCH STAGE THE CORE BROKE ONLY

16 Carrier m/c

COVER 16 carriers in use

8 car with 1 end of 113 poly 8 car with 1 end of 110 dyneema

CORE 1 end of 190/1/3 with 10 TPI "S" and 7 TPI "Z"

PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	26.82	11.293	3803	0.582	11.15	
Dye	25.56	10.5		0.582	14.7	
Stretch at 5%	26.84	10.58		0.587	9.9	15.3
Finish	24.35	11.95	3703	0.55	11.2	

DT PA26 SAMPLE COMMENTS: CORE BROKE IN FIRST TWO READINGS ,WHOLE BRAID BROKE IN THIRD

16 Carrier m/c

COVER 16 carriers in use

8 car with 1 end of 113 polyester 8 car with 1 end of 110 Dyneema

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	21.82	10.953	3908	0.681	5.28	
Dye	23.62	12.26		0.693	10.1	
Stretch at 5%	24.56	11.79		0.573	5.8	15.3
Finish	21.48	12.87	3786	0.578	6	

DT PA27 SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER, STRAIGHT PULL CORE BROKE COVER STAYED INTACT.

16 Carrier m/c

COVER 16 carriers in use

16 car with 1 end of 113 Polyester per carrier

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 44

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	19.14	9.037	4033	0.549	5.9	
Dye	16.18	8.35		0.548	8.5	
Stretch at 5%	16.49	6.54		0.545	5.5	15.3
Finish	16.12	8.04	3919	0.553	5.6	

If I can be any further assistance please do not hesitate to contact me

Kind regards

Brian Hallett

Brian Hallett

Product Development Manager

BROOKSTEIN DECLARATION EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware Corporation,

Defendant.

_____/

DEPOSITION OF: ASHLEY HOLLOWAY

DATE: September 15, 2005

TIME: 1:08 p.m. to 5:07 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Les Smoak, CLVS

30

1 suture --
2 A. Correct.
3 Q. -- with respect to knot security; is that right?
4 A. Correct.
5 Q. Okay. Does Arthrex test its FiberWire sutures
6 for pliability?
7 A. No.
8 Q. Do you know what pliability means?
9 A. Pliability --
10 Q. As it relates to FiberWire sutures?
11 A. I don't know the exact definition, no.
12 Q. But Arthrex does not test its FiberWire sutures
13 for pliability?
14 A. No.
15 Q. Has it ever tested its FiberWire sutures for
16 pliability?
17 A. Not that I'm aware of.
18 Q. Does Arthrex test its FiberWire sutures for
19 handleability?
20 A. Yes.
21 Q. How does Arthrex test its FiberWire sutures for
22 handleability?
23 A. It's a subjective test.
24 Q. What do you mean by that?
25 A. I mean basically we give a piece of suture to a

31

1 product manager or a surgeon who is familiar with the
2 field of sutures and ask them to give us feedback on the
3 handleability.
4 Q. And what is handleability measured in?
5 A. There are no units. It's subjective.
6 Q. So what does "handleability" mean? What does the
7 definition of "handleability" mean as Arthrex uses that as
8 a test for its FiberWire sutures?
9 A. What do I think it means?
10 Q. What does Arthrex think it means?
11 A. I think handleability as is it easy to move
12 through the tissue or pass through the tissue? Is it easy
13 to slide knots? Is it easy to tie knots?
14 Q. Anything else?
15 A. Is it easy to slide through the anchor eyelet?
16 Q. Anything else?
17 A. Not that I can think of.
18 Q. Do materials contribute to the handleability of
19 Arthrex's FiberWire sutures?
20 MR. TAMBURO: Objection to form.
21 A. Yes.
22 MR. TAMBURO: Also, it's outside the scope.
23 Q. What materials contribute to the handleability of
24 Arthrex's FiberWire sutures?
25 A. All materials used.

32

1 Q. What do you mean by that?
2 A. I mean everything that's in that construct.
3 Q. Contributes to the handleability of the suture?
4 A. Yes.
5 Q. What is the handleability of Arthrex's FiberWire
6 suture?
7 MR. TAMBURO: Objection to form.
8 A. Do you want me to give you a subjective answer?
9 Q. Let me rephrase the question. Has Arthrex
10 received feedback from surgeons on the handleability of
11 Arthrex's FiberWire suture?
12 A. Yes.
13 Q. And what was the feedback that Arthrex received
14 from surgeons on the handleability of Arthrex's FiberWire
15 suture?
16 A. That it's easy to utilize.
17 Q. And what surgeons provided that feedback?
18 A. I have heard Dr. Burkhart say that.
19 Q. Anyone else?
20 A. Not directly to me, no.
21 Q. Have any doctors provided negative feedback to
22 Arthrex on the handleability of Arthrex's FiberWire
23 suture?
24 A. Yes.
25 Q. How many doctors have provided negative feedback

33

1 to Arthrex on the handleability of Arthrex's FiberWire
2 suture?
3 A. I know of only one account.
4 Q. And who was that?
5 A. I believe, again, it might have been Dr.
6 Burkhart.
7 Q. And what negative feedback did Dr. Burkhart
8 provide to Arthrex on the handleability of Arthrex's
9 FiberWire sutures?
10 A. That the nylon was too repetitious in the
11 TigerWire.
12 Q. What does that mean?
13 A. It means there were too many wraps.
14 Q. And that affected the handleability of the
15 suture?
16 A. That affected the feel.
17 Q. Is the feel like handleability, or is that
18 another word for handleability -- feel?
19 A. Feel would fall under handleability; how does it
20 feel in your hands.
21 Q. All right. So that's one criteria used for the
22 handleability?
23 A. Right.
24 Q. As well as passing the suture through tissue or
25 any other things you described?

BROOKSTEIN DECLARATION EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC.,
a Massachusetts corporation,

Plaintiff,

v. Case No: CA-0412457-PBS

ARTHREX, INC, a
Delaware corporation,

Defendant.
_____/

VIDEOTAPE DEPOSITION OF ANN WATERHOUSE

TAKEN: Pursuant to Notice by
Counsel for the Plaintiff

PLACE: Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34109

DATE: Wednesday, August 24, 2005

TIME: Began: 8:55 a.m.
Ended: 1:00 p.m.

BEFORE: TRACIE L. MOUNTAIN-THOMPSON
Court Reporter
Notary Public
State of Florida at Large

Page 46

Q What does that mean?
A In the first paragraph, under suture weight, which is coating, it says, "Pearsalls makes the following statement about the NuSil coating applied to both our Arthrex FiberWIRE and other competitive product."
So they're demonstrating their processing of that coating by the statement that follows.
Q That statement is from NuSil, not from Arthrex?
A No. That's from Pearsalls.
Q All right. But just to be clear, the coating on the FiberWIRE product is MED-2174, right?
A Correct.
Q Okay. And in that last paragraph on page 2104, the second sentence says, "As noted (above) we cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures, and other parameters for the coating process. For each coating batch all these details are recorded in the batch documentation available to you and other customers."
Do you see that?
A Yes.
Q What does that mean?

Page 47

A That means that that's the processing that they -- they put onto our product and it's describing that they do it to a certain viscosity. They do it at a certain speed and temperature. And they have other parameters for the coating process. So that coating process is an agreed upon process by their buyers, basically, so that's what it is. That's how it's actually done.
Q Does Arthrex and Pearsalls have an agreed -- an agreed detailed coating process?
A Not that I know of.
Q So how does Arthrex know how the FiberWIRE coating is applied to its FiberWIRE product?
A Specifically, they could ask for that batch record for each lot that is produced, but in general, they know the coating process because of the temperature and speed, and the parameters that Pearsalls uses coats that in an even manner, so it's an assumption.
Q Is it true that Pearsalls cannot measure the amount of coating on the FiberWIRE product?
MR. SABER: Objection. Inconsistent with the testimony.
BY MR. FALKE:
Q I'm just looking. It says -- on page 2104 it says, "We," and I assume that's Pearsalls; is that right?

Page 48

A Correct.
Q "We," Pearsalls, "cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures and other parameters for the coating process."
A Correct.
Q So does Arthrex accept batches of FiberWIRE based on the coating?
MR. SABER: Objection. Vague. Confusing question.
BY MR. FALKE:
Q All right. Was Pearsalls representing to Arthrex that it cannot measure the amount of coating on the FiberWIRE product when Arthrex submitted this statement to the FDA in Exhibit 81?
A Can you repeat the question.
Q Sure.
Was Pearsalls representing to Arthrex that Pearsalls cannot measure the amount of coating on the FiberWIRE product when Arthrex submitted Exhibit 81 to the FDA?
A Yes, as a percentage.
Q As a percentage of what?

Page 49

A The total weight of the suture.
Q Has Arthrex submitted any document to the FDA in any submission which details the coating process Pearsalls uses to coat any FiberWIRE suture?
A No.
Q Why not?
A Because we used the statement as a reference point so that we didn't have to submit anything about the coating process. We described it instead.
Q You say "the statement," which statement is that?
A On 2104, the statement that Pearsalls makes.
Q Okay. And then it says, in the last sentence on page 2104, "For each coating batch all these details are recorded in the batch documentation available to you and other customers."
Do you see that?
A Yes.
Q Is the reference to "you" in that sentence, does that refer to Arthrex?
A Correct.
Q Does Arthrex have any documents which reflect the details of the coating process for the batches of FiberWIRE it receives?
A Not that I know of.

Page 50

Q Does Arthrex have the ability to obtain those documents?
A Yes.
Q So Pearsalls can determine the percentage -- cannot determine the percentage of coating to the total weight of the suture; is that right?
A Correct.
MR. SABER: Objection. Vague.
BY MR. FALKE:
Q I'm sorry, what was your answer?
A Correct.
Q And the reason they can't do that is because they can't measure the amount of coating on it; therefore, they can't measure the percentage of the amount of coating to the total weight, right?
A Correct.
Q I'm going to reask that question because the record is slightly unclear. So Pearsalls cannot determine the percentage of coating to the total weight of the suture; is that right?
MR. SABER: Could you read that question back, please.
(The court reporter read back the requested portion of testimony.)
MR. SABER: Objection. Vague. Asked and

Page 51

answered.
BY MR. FALKE:
Q You can answer.
A Correct.
Q Okay. If you could turn to page 2130, please, in Exhibit 81.
I'm sorry, are you there?
A Uh-huh.
Q If you look at the last paragraph on that page, 2130, and in particular, the last sentence, it says -- excuse me, let me step back. The second to the last paragraph on page 2130, it says, in the last sentence of that paragraph, "The dyed polyester suture (D & C Blue No. 6) and di-peroxide silicone oil (coating) are pharmacologically inactive."
Do you see that?
A Yes, I do.
Q Does the di-peroxide silicone oil (coating) refer to the MED-2174 that's applied to the FiberWIRE product?
A Yes, it does.
Q And what does that mean "pharmacologically inactive"?
A Pharmacologically inactive means that it does not cause any reaction when tested.

Page 52

Q What do you mean by "when tested"?
A We test according to 10993, which is cited in that paragraph.
Q Uh-huh.
A There are certain tests that you have to perform according to that based on the use of your product. When they test that, as an example -- and you've got both of the tests -- they test whether there is a reaction or -- a negative reaction or an adverse reaction as opposed to nothing happening.
Q Right.
A If it -- if there is nothing happening, they consider that pharmacologically inactive.
Q Has Arthrex made any representation to the FDA in any submission as to whether MED-2174 is absorbable in the body?
A No.
Q Do you know if MED-2174 is absorbable in the body?
A No.
Q No, you don't know?
A I don't know.
Q I think I asked this but I'm going to ask it again. And Exhibit 81 was submitted to the FDA by Arthrex, right?

Page 53

A Yes, it was.
(Exhibit 82 was marked for identification.)
BY MR. FALKE:
Q Let me hand you Exhibit 82, which is a document with Bates numbers ARM001882 through 1884. Have you seen this document before?
A Yes, I have.
Q And what is Exhibit 82?
A This is the substantial equivalence letter for K010673.
Q And that reference, that K number, 010673, reverts to Exhibit 78, right?
A Correct.
Q And what is the purpose of this substantial equivalence letter, Exhibit 82?
A It's the FDA's way of granting you permission for sale of a product.
Q Okay. So through Exhibit 82 the FDA was granting Arthrex the permission to sell Arthrex FiberWIRE; is that right?
A Correct.
Q And Exhibit 82 is dated May 14th, 2001; is that right?
A Correct.
Q Did Arthrex sell FiberWIRE prior to May 14th,

BROOKSTEIN DECLARATION EXHIBIT 19

Arthrex.

April 26, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Mr. David Krause
Department of Health and Human Services, Public Health Service
Division of General & Restorative Devices
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: Amendment to Original Pre-Market Submission 510(k) #K010673, Arthrex FiberWIRE™

On February 28, 2001 the Arthrex FiberWIRE™ was submitted to the FDA. Per a conversation between Ann Waterhouse (Arthrex) and David Krause (FDA) on April 16, 2001, the following is being sent as amendment information. Specifically included are percentages for content, labeling amendments, and research data for accessory equipment.

Arthrex has submitted in duplicate the requested information and respectfully asks that these be accorded the same confidentiality as the original submission, K010673. We request that the Food and Drug Administration keep confidential all information outside of the 510(k) summary and indications for use.

Should the following information be in any way deficient, please let us know. We will be happy to provide you with any missing details or information. Should you have further questions concerning the amendment we have submitted, please contact either Vernon Brown or Ann Waterhouse at (941) 643-5553. Thank you.

Sincerely,

Ann Waterhouse
Regulatory Affairs Specialist

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

ARM 002103

1. **In many places in the document the suture is described as being composed of polyester and ultrahigh molecular weight polyethylene (UHMWPE). Please describe the polyester and indicate what percentage of the suture weight is UHMWPE. Also, what percentage of the weight of the suture is the dye and what percentage of the weight of the suture is the coating?**

Description of the polyester:
The Polyester used by Pearsalls to produce Arthrex FiberWIRE™ is created from high tenacity filaments of Polyethylene Terephthalate. Specifically, this is type 712 polyester that is manufactured by KoSa GmbH & Co KG.

% of the suture weight which is Ultra high molecular weight polyethylene:
Broken into percentage, the Polyester is 38.09% of the suture input and the Polyethylene (UHMW) is 61.91%.

Suture weight which is dye:
In using an accepted dye, D&C Blue No. 6, neither Pearsalls nor Arthrex measured the percentage of weight which the suture gained by the dye process. Pearsalls certifies that the process with which they dye the polyester conforms with the 2.0 Cupric Sulfate listed in the USP Matching Solutions table on page 1585 of USP 24. Also, Pearsalls certifies to all of it's customers that the D&C Blue No. 6 is a FDA approved dye.

Suture weight which is coating:

Pearsalls makes the following statement about the NuSil coating applied to both our Arthrex FiberWIRE™ and other competitor product:

"The coating is a silicone rubber known as NuSil 2045. It is identical to the coating we apply for Davis & Geck silk suture, and is also used to coat "Ticron" polyester suture. As noted (above) we cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures, and other parameters for the coating process. For each coating batch all these details are recorded in the batch documentation available to you and other customers."

2. **You describe your suture as having a silicone elastomer coating. Please identify a legally marketed suture predicate that is coated with silicone.**

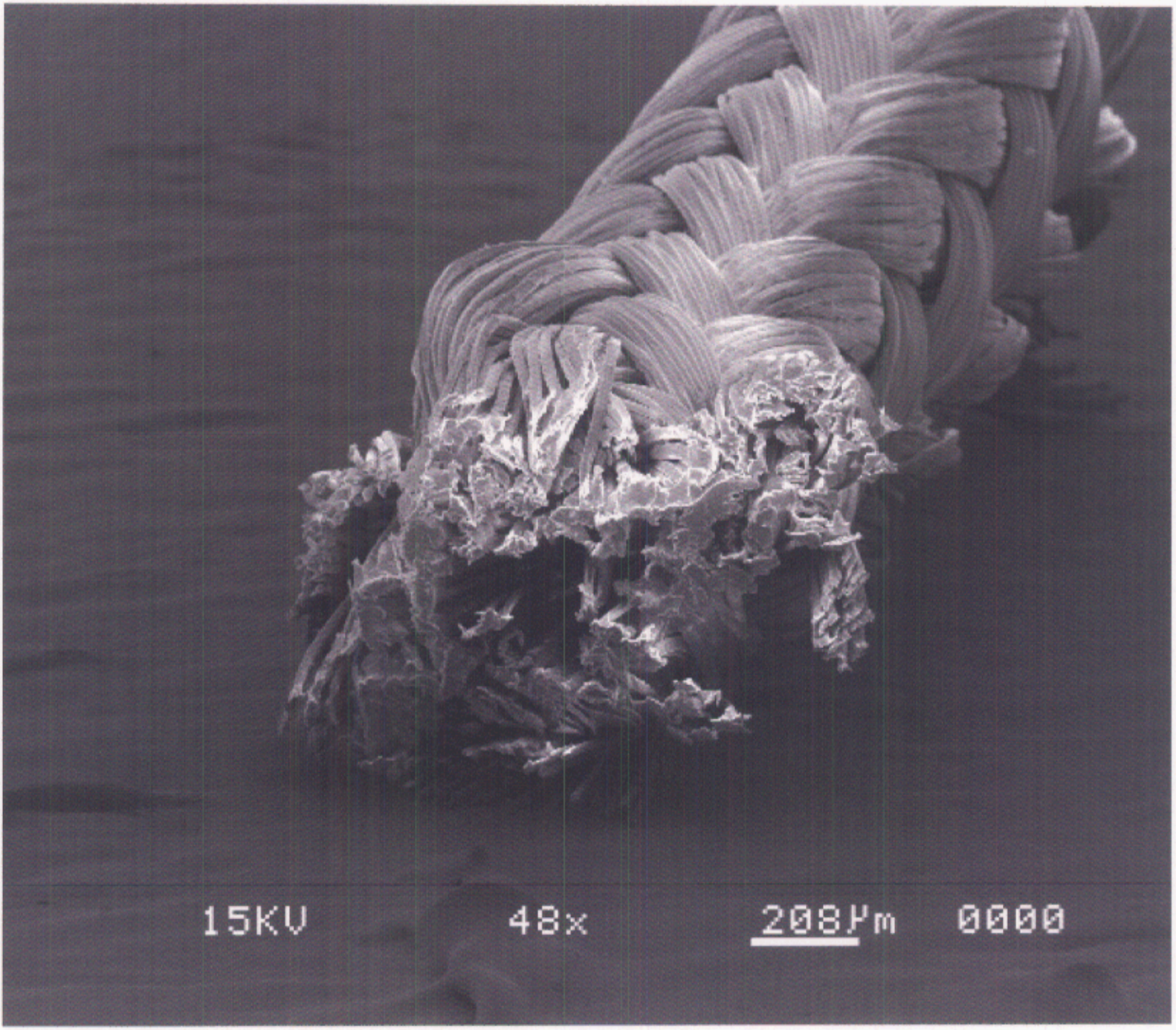
The predicate devices with Nu-Sil silicone derivative or equivalent, used to coat silk and polyester suture are listed below. The 510 (k) summaries or statements for these predicate products are contained in the following pages:

K930586	Dermalon, Surgilon, Ophthalon, & Ophthalmic Suture
K930590	Silk Sutures
K961925	Polyester Non-Absorbable Surgical Suture
K990088	Synthofil Non-Absorbable PET Surgical Suture
K001172	Polyester Non-Absorbable Surgical Suture
K003590	Grams Polyester Non-Absorbable Suture

BROOKSTEIN DECLARATION EXHIBIT 20


15KV
48x
208µm
0000

BROOKSTEIN DECLARATION EXHIBIT 21


15KV
48x
208µm
0000